

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/744,654	LAPIDOT ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Anne Marie S. Wehbe	1633	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Applicant's amendments filed on 2/10/06 and 3/14/06.
2. ☒ The allowed claim(s) is/are 123-126 and 128-131.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |   |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                       |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input type="checkbox"/> Examiner's Amendment/Comment  |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance              |
|   | 9. <input type="checkbox"/> Other _____.  |

### **DETAILED ACTION**

Applicant's amendments filed on 2/10/06 and 3/14/06 have been entered. Claims 1-122 and 127 are canceled. Claims 123-126 and 128-131 are currently pending in the instant application.

Applicant's amendment, arguments, and supporting evidence have overcome the previous grounds of rejection of the claims under 35 U.S.C. 103(a) over Kanz et al. in view of Mohle et al., see the Reasons for Allowance below.

#### ***Interview Summary***

It is noted that in a telephonic interview on 3/10/06 initiated by the examiner, the applicant was notified that the amendment filed on 2/10/06 had been entered, but that the application was not in condition for allowance because the specification was not in compliance with 37 CFR 1.821-1.825 in view of several sequences on page 40 of the specification which were not identified by SEQ ID NOS. The applicant agreed to submit a sequence listing in compliance with 37 CFR 1.821-1.825 including these sequences and to amend the specification on page 40 to reference the appropriate SEQ ID NOS. During the same interview the applicant agreed to amend claims 123 to add the word "human" in the body of the claims to clarify that the stem cells referred to in the method steps are the human stem cells referred to the preamble. Also, the applicant agreed to amend claim 125 to remove the sole reference to CD38-/low, which

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applicant indicated was a typographical error. Since the applicant was required to submit an amendment for the sequence listing, the applicant indicated the agreed upon changes to the claims would also be submitted with the sequence listing.

***Nucleotide and/or Amino Acid Sequences***

Applicant's submission of a sequence listing in paper form and CRF on 3/14/06 is acknowledged. This application is now in compliance with 37 CFR 1.821-1.825.

***Reasons for Allowance***

The following is an examiner's statement of reasons for allowance: applicant's submission of the Brugger et al. reference provided evidence in support of applicant's argument that Kanz et al. teaches away from stimulating less than 6 days. The rejection of the claims under 35 U.S.C. 103 over Kanz et al. in view of Mohle had been maintained because Kanz teaches the stimulation of the cells with the growth factor for up to 28 days, a range of time which the examiner argued included five days or fewer, such that the recited range in the claims was encompassed by the range taught by Kanz. The applicants successfully traversed this grounds of rejection by submitting Brugger et al., a prior art reference on which Kanz is an author, which shows that expansion of CD34+ cells does not occur up to six days of incubation of the CD34+ cells with the preferred combination of factors described by Kanz. It is agreed that the Brugger et al. publication demonstrates that Kanz et al. would not have provided motivation for stimulating

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CD34+ cells with a growth factor for less than 6 days, since Kanz et al. teaches stimulating the cells for a period of time that allows cell expansion. Claims 123-126 and 128-131, which contain the limitation that the cells are stimulated for up to five days, are therefore considered free of the prior art of record and allowable.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. If the examiner is not available, the examiner's supervisor, Dave Nguyen, can be reached at (571) 272-0731. For all official communications, **the new technology center fax number is (571) 273-8300**. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197.

Representatives are available daily from 6am to midnight (EST). When calling please have your

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application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D  
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Anne M. Wehbe', with a long horizontal stroke extending to the right.